

REMARKS

Claims 52, 69, 76, 97, 98, 100, 106 and 108 have been amended. No new matter is added by the amendments to the claims. Applicants retain the right to pursue the canceled subject matter in a divisional application. Claims 20, 21, 51, 67, 68, and 90-96 are withdrawn as directed towards non-elected subject matter. Claims 1-110 are pending.

Restriction Requirement

In the Office Action (Paper No. 102803, page 2-3), the Patent Office maintained the restriction between groups I and III and maintained the restriction among the various fragments of VEGF-2. Subsequently, Applicants discussed the Restriction Requirement with Gary Kunz via telephone. In this telephone conversation, it was agreed that the restriction between groups I and III and the various fragments of VEGF-2 should be withdrawn (See, Examiner Initiated Interview Summary, dated April 12, 2004). To address the reversal of the Restriction Requirement, Gary Kunz instructed Applicants to respond to the present Office Action (Paper No. 102803) and indicate that the Restriction had been removed.

Applicants also reiterate the request for rejoinder made in Applicant's Response to the Restriction Requirement mailed August 22, 2003. Applicants note that the withdrawn method claims (claims 20, 21, 51, 67, 68, and 90-91) all depend from a pending composition claim. As such, each of the withdrawn method claims include all the limitations of the composition claims.

Information Disclosure Statement

Applicants submit herewith a Supplemental Information Disclosure Statement with a Form PTO/SB/08 that provides the complete citations for references AF-AM, FR, DW and EB.

Specification

The specification was objected to for not including a reference to SEQ ID NO: in Figure 1 or its Brief Description. Figures 1A-1D were also objected to for reciting the language "match with Figure..." Applicants have amended the Brief Description of the Figures and Figures 1A-1D to address the Examiner's concern. Applicants respectfully request removal of this objection.

The specification was also objected to as not indicating the current status of all priority documents. Applicants have amended the first line of the specification to indicate the status of all priority documents and therefore request withdrawal of this objection.

The title of the invention was objected to as not descriptive. Applicants submit that the amendment to the title overcomes this objection.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claims 52-66, 69-89 and 97-110 were rejected under 35 U.S.C. § 112, first paragraph as not enabled for failure to comply with the deposit requirements of the Budapest Treaty. In response, Applicants submit the following statement regarding the availability of the Deposit:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on May 12, 1995, accepted by the ATCC, and given ATCC Accession Number 97149. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 97149 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 97149 is enclosed herewith as Exhibit A.

Applicants also wish to point out that ATCC Deposit No. 97149 was released for general distribution on October 27, 1999. See Exhibit B.

Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 were rejected under 35 U.S.C. § 112, first paragraph as not enabled for the term "specifically binds." In particular, the Examiner maintains that "it is not understood how Applicants can make a protein which binds to only the desired peptide and to no other peptides." Applicants respectfully traverse.

Claim terms are to be given their broadest reasonable interpretation, consistent with the specification and consistent with the interpretation that one skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999). There is a "heavy presumption" that terms used in claims have the ordinary meaning that would be attributed to those words by persons

skilled in the relevant art. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366, 62 USPQ2d 1658, 1662 (Fed. Cir. 2002); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362-63, 52 USPQ2d 1001, 1004 (Fed. Cir. 1999); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988). Determining the meaning of a technical claim term must not be done in a vacuum, but always in light of the teachings of the prior art, the disclosure as it would be interpreted by one having of skill in the art, and the statements made during prosecution. *In re Moore*, 439 F.2d 1232, 1235 and n.2 (CCPA 1971). Further, a particular form of disclosure is not necessary to describe claimed subject matter, only a description that clearly allows persons of ordinary skill in the art to recognize that the inventor was in possession of what is claimed. *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q2d 1578, 1581 (Fed. Cir. 1996). Thus, a crucial step in determining the meaning of a technical claim term is to determine the ordinary meaning that would be ascribed by a person skilled in the relevant art.

To address this rejection, Applicants respectfully direct the Examiner to Declaration of Viktor Roschke, submitted herewith. In his Declaration, Dr. Roschke defines the phrase "specifically binds" as understood by one of skill in the art. As defined by Dr. Roschke, "a 'specific antibody' is one that is discriminating in that it preferentially binds the antigen against which it was raised/screened, compared to its ability to bind other antigens." (Roschke Declaration, paragraph IIC). The specificity of an antibody, i.e., the antibody's "ability to detect a given antigen in the presence of other antigens" is what makes "antibodies useful as agents of the immune system, as tools in biological assays, and as therapeutic agents. (Roschke Declaration, paragraph IID). As discussed by Dr. Roschke, those of skill in the art routinely use the phrase "specifically binds" to refer to the functional ability of an antibody to preferentially bind a particular (target) antigen instead of a non-target antigen (Roschke Declaration, paragraph IIIA), even though the antibody "could (and can) be made to bind non-target antigens by utilization of non-optimal antibody binding conditions" (Roschke Declaration, paragraph IIIB). According to Dr. Roschke, "[o]n and before March 8, 1994, the description of antibodies as 'specifically binding' a particular antigen was routinely used, recognized and understood by those who ordinarily practiced research with antibodies" and that "[m]ethods for determining antibody specificity were well known." (Roschke Declaration, paragraph IVA).

Applicants respectfully submit that the term "specifically binds" as used in the claims has a definite meaning that would be understood by one of skill in the art. A skilled artisan would therefore understand how to make and antibody that "specifically binds" the protein of the invention. Applicants therefore request withdrawal of this rejection.

Claims 52, 54, 58-66, 69, 71, 74-76, 78, 82-89, and 97 were rejected under 35 U.S.C. § 112, first paragraph as not enabled for antibodies that bind the "mature" form of VEGF-2. Although Applicants traverse this rejection, the language "mature" has been deleted from the claims. Applicants therefore request withdrawal of this rejection.

Claims 98, 100, 106 and 108 were rejected under 35 U.S.C. § 112, first paragraph as not enabled for the phrase "pharmaceutically acceptable carrier." As suggested by the Examiner, Applicants have the claim to recite "carrier." As acknowledged by the Examiner, the term "carrier" broadens the scope of the claims, because the limitation encompasses pharmaceutically acceptable carriers. Applicants submit that the amendments to the claims overcome this rejection.

Written Description

Claims 52, 54, 58-66, 69, 71, 74-76, 78, 82-89, and 97 were rejected under 35 U.S.C. § 112, first paragraph as lacking written description for antibodies that bind the "mature" form of VEGF-2. Although Applicants traverse this rejection, claims 52, 69, 76 and 97 have been amended to remove the term "mature."

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for reciting the term "specifically binds." Applicants respectfully traverse.

In response to this rejection, Applicants again direct the Examiner to the Declaration of Viktor Roschke, discussed above. As discussed above, claim terms are to be given their broadest reasonable interpretation, consistent with the specification and consistent with the interpretation that one skilled in the art would reach. One of skill in the art would understand

the term "specifically binds" to refer to an antibody that preferentially binds the antigen against which it was raised/screened, compared to its ability to bind other antigens. The phrase "specifically binds" is routinely used by those of skill in the art and would not be considered indefinite. Therefore, this rejection is improper. Applicants respectfully request withdrawal of this rejection.

Double Patenting

Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66, 69-89 and 97-110 were provisionally rejected over claim 19 of copending Application No. 09/499,468; claim 14 of copending Application No. 10/060,523; claim 20 of copending Application No. 10/120,398; claim 21 of copending Application No. 10/120,377; and claim 21 of copending Application No. 10/120,414.

Applicants note that claim 19 of Application No. 09/499,468 has been canceled. Therefore, this rejection is improper with respect to this copending application.

With respect to the remaining applications, Applicants will consider filing a Terminal Disclaimer in the present application over the any of claims 20, 21 or 21, as currently pending in U.S. Application No. 10/120,398; 10/120,377 and 10/120,414, respectively, if any of claims 20, 21 or 21 issue prior to allowance the currently pending claims in the instant application. Alternately, Applicants will consider canceling some or all of the cited claims in the copending applications.

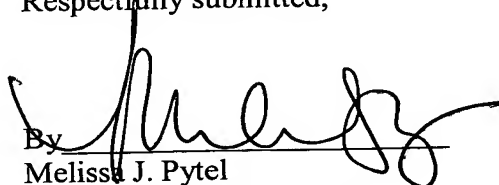
CONCLUSION

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: April 26, 2004

Respectfully submitted,

By 

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PF112P2



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10801 University Boulevard
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Telephone: 703-365-2700

FACSIMILE

Date: October 27, 1999

To: Dr. James Davis
HGS, Inc.

City & Country: Rockville, MD

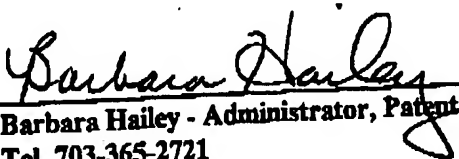
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Total number of pages including this page: 1

From: ATCC Patent Depository

ATCC Patent Depository Fax Number: 703-365-2745

Reference: Further to our communication to you of September 27, 1999, since we have not heard from you to the contrary, ATCC 75698 and 97149 (cited in U.S. Patent #5,932,540 dated August 3, 1999) have been released for general distribution effective October 27, 1999.


Barbara Hailey - Administrator, Patent Department
Tel. 703-365-2721

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American Type Culture Collection

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc.
Attention: Robert H. Benson
9410 Key West Avenue
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor:

ATCC Designation

DNA Plasmid, 567,663 (HGS Docket PF112P1)

97149

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above.

The deposits were received May 12, 1995 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

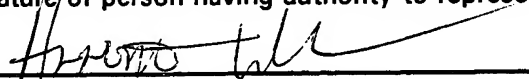
If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 18, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:


Annette L. Bade, Director, Patent Depository

Date: May 22, 1995

cc: Greg D. Ferraro